SCIENCE IN POLITICAL AGENDAS

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Brian Roberts, PhD Thesis Supervisor Department of Government The University of Texas at Austin	Date
_____	_____
Rebecca A. Wilcox, Ph.D. Second Reader Honors & Scholarships, College of Natural Sciences The University of Texas at Austin	Date

Table of Contents

ACKNOWLEDGEMENTS III

ABSTRACT IV

INTRODUCTION 1

BACKGROUND 4

ANALYSIS OF SIGNIFICANT HISTORICAL POLICY EVENTS 8

OBSTACLES TO PROACTIVE POLICY ADVOCACY ERROR! BOOKMARK NOT DEFINED.

CREATING THE SOLUTION: AN EVOLVING WORLD OF RESEARCH ETHICS ADVOCACY 21

CONCLUSION 26

REFERENCES 29

AUTHOR BIOGRAPHY 35

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Abstract

Ethical conduct in human subjects research is primarily enforced by the federal government through regulations from agencies like the Food & Drug Administration or Department of Health and Human Services and the U.S. Congress. Throughout the 20th century, widely publicized events like the Tuskegee syphilis scandal and the diethylstilbestrol tragedy provided the impetus to create or improve research ethics regulations. However, increased regulation results in decreased probability of future triggering events from occurring; thus, the primary driver of research ethics policy is destined to fade over time. As less extreme triggering events fail to push legislators into action, research ethics policy will progress at an unacceptably slow pace. The field of bioethics has yet to establish a sustainable advocacy infrastructure meant to advance the recommendations of bioethicists in the field, but doing so is necessary to fill the void in political momentum left by extreme triggering events. Through a literature review and analysis of primary government documents, I evidence current dependence on triggering events and advocate for the creation of a new driver of progress, namely, a nonprofit research ethics advocacy organization. This entity would be able to provide proactive research ethics policy recommendations, thus allowing the federal government to better address issues in this area when triggering events do arise. Existing bioethics academic centers and professional organizations, such as the Hastings Center or the American Society for Bioethics and Humanities (ASBH), are best prepared to develop an advocacy group. Current policy stakeholders in the research ethics sphere are either institutions of higher education or medical interest groups, both of which have a broad array of interests that prevent them from regularly prioritizing improved ethics regulations in their advocacy

efforts. A shift in this niche policy area is necessary in order to continue the push to improve human subjects protection policy going forward.

Introduction

For every policy issue, there is a reason why it caught the attention of policymakers. When thinking about major issues like healthcare and taxation, it is relatively easy to surmise the logic; they affect the daily lives of nearly every American citizen, and thus factor significantly into voters' considerations of political candidates. However, essentially any part of life has the potential to garner legislative attention, should the proper conditions fall into place. What, then, is necessary for a policy issue to get on the political agenda? In the case of research ethics, issues typically come to the fore as a byproduct of newsworthy events that concisely and abruptly explain a problem to a wide audience. With the exception of such circumstances, research ethics is a technical and esoteric field that few laypeople and, for that matter, policymakers, understand. Unfortunately, this knowledge gap makes creating well-crafted laws and regulations difficult for policymakers in the wake of triggering events demanding legislative attention.

Research ethics is one of three main branches within the academic field of bioethics. Accompanied by medical ethics and public health ethics, it addresses the moral components of how researchers in various fields conduct their work. It is at this point that the scope of bioethics may become ambiguous, as research ethics may be understood as the ethics of any research done on any life form. For the purposes of this study, research ethics issues in policy will be defined as areas pertaining to medical or pharmaceutical research done on humans or whose results will affect humans. The federal government is the primary body through which research conduct is regulated; therefore, it is important to know what drives Congressional and federal agency interest in policy issues relevant to research ethics.

As the fields of biomedical and pharmaceutical research expanded in the twentieth century following World War II, so too did a reckoning with their human impacts. Major

historical areas of research ethics include human subjects' protection, the inclusion of relevant populations in research studies, and the extent of trial research necessary for an experimental product to be considered safe and effective. The United States' modern history is rife with ethics violations in the name of research, as well as debates over proper ethical guidelines to govern research. The Tuskegee syphilis scandal from 1932 to 1972 saw an abuse of power by the U.S. National Public Health Service that took advantage of poor, uneducated black men in the rural South for forty years (Jones, 1993). It was not until 1993 that the Food and Drug Administration began requiring pharmaceutical testing on both men and women; thus, drugs approved prior to then were not necessarily tested for different side effects and proper dosage by sex (Hilts, 1993, p. B8). It was not until after the late 1950s and early 1960s, when the offspring of women who had taken the sedative Thalidomide while pregnant were born with significant developmental defects, that regulatory requirements for proving the safety of new drugs were put in place (Kim, 2011). These and other examples are landmark events for a nation trying to balance the benefits of a biomedically advanced society with the proper ethics guidelines needed to regulate this progress.

A large number of the most prominent policy events regarding research ethics were initially responses to tragedies or scandals. Some of these events are expounded upon in a later section of this thesis in order to illustrate this point. Large-scale catastrophes are considered a type of focusing, or triggering, event. Foundational literature in the field of agenda-setting, particularly Kingdon 1995, argues that focusing events distill abstract and complex issues into a discrete problem easily understandable to the public. Research ethics as a subject is not generally newsworthy, nor is it easily digestible for non-experts. The sudden introduction of an issue through a catastrophic event, usually carried out by the media, increases the probability that

people – either regular citizens or politicians – will consider the issue important (Vane and Kalvas, 2013). A shift in the priorities of the public and politicians can result in subsequent policy change to fix or ameliorate the problem. This historical trend implies that triggering events may be necessary for issues in research ethics to be included in the United States policy agenda. Such a system introduces a problematic cycle that affects the future of research ethics policy progress. As regulation increases, the likelihood and severity of triggering events decreases, thus decreasing political attention given to research ethics issues. In periods of wide deregulation, there is currently no strong opposition to important policy being taken away. In the absence of a steady presence advocating for responsible and modern research ethics policy, the United States is doomed to a cycle in which no proactive and progressive policy is made.

There is a need to increase proactive research ethics advocacy at the federal level in order for progress in research ethics policy to continue. As a policy area, bioethics issues are blended into health and STEM advocacy work. While institutions of higher learning, medical groups, and departments of health and human services from the fifty states all make their voices heard in research ethics policy debates, each of these entities has a myriad of other policy concerns that overlap with and take priority over support for stringent ethics requirements. These often include financial interests and efficiency of the research process. Research ethics issues must compete for prioritization with often more lucrative or otherwise advantageous focus areas, like increased research funding and changes to the national healthcare policy. Moreover, it is unlikely that policymakers will turn their attention to research ethics unless concern arises through a triggering event. As such, this thesis argues the need to establish an independent non-governmental body whose sole purpose is to provide sound policy recommendations when they

are needed, in order to improve the federal government's response to triggering events and serve as a cautionary voice during waves of widespread deregulation.

While a majority of regulations on research come from federal agencies like the Health and Human Services Department and the Food & Drug Administration, mandates to do this work often come from Congress. As the legislative branch is generally the most responsive to advocacy and lobbying efforts (especially in the wake of a triggering event), this thesis focuses on the Congressional side of research ethics policymaking. In order to justify the need to establish an independent advocacy body that reduces the dependence of research ethics policy progress on these major triggering events, this thesis seeks to create a bird's-eye view of major policy action relevant to research ethics in the United States Congress from 1905 to the present, beginning with the Pure Food and Drug Act. In addition, this thesis highlights the obstacles facing advocacy efforts in the research ethics arena and explore possible remedies.

Background

The formal field of bioethics is quite young, having only been established as an academic discipline in the 1960s and 1970s (Callahan, 2012). Prior to its founding, religious leaders, particularly Catholics, were the primary voices of morality in scientific and medical issues. Bioethics is now an interdisciplinary field comprised of ethicists, scientists, physicians and other medical practitioners, lawyers, and many others. This growth resulted from the explosion of biomedical advancements that occurred during and following World War II. Inventions such as the cardiac pacemaker, dialysis machines, and oral contraceptives spurred a larger conversation about the proper limits to medical interventions as human capacity to alter nature's course rapidly expanded. As is aptly stated by Lee and McCarty, "Scholars have debated whether

bioethics is a discipline with its own methods and theoretical grounding, a multidisciplinary field bringing various professional perspectives to bear on particular types of problems, a set of problem-solving skills to resolve moral disagreements, or something else entirely" (Lee and McCarty, 2016, p.19). For the purposes of this paper, it is immaterial whether bioethics meets a strict definition of an academic discipline, beyond an acknowledgement that most people currently interested in the field are academics. Bioethics, and research ethics in particular, is relevant to the current investigation as a body of knowledge crucial to the development of appropriate regulations that govern scientific research in the United States.

Research ethics is one of three major branches of bioethics which, broadly defined, is the study of ethics within the biological sciences. The other two branches are medical ethics and public health ethics. The former is concerned with an array of issues within medical practice, such as the doctor-patient relationship and abortion. The latter deals with ethical dilemmas in the public health sphere. Research ethics, predictably, confronts ethical issues in the course of all kinds of research, including academic and pharmaceutical. Though research ethics primarily focuses on conduct during biological and biomedical research, it includes any research involving human or nonhuman subjects.

While the advent of bioethics is typically attributed to the rapid biomedical advancements brought about by World War II, one can argue that specifically research ethics as a policy issue actually began at the beginning of the twentieth century during the Progressive Era. The passage of the Pure Food and Drug Act of 1906, which banned the sale of adulterated or misbranded food and drugs – terminology that includes untested drugs – was part of a larger Progressive movement that encouraged increased use of the scientific method. This law was the first in the United States to require that pharmaceutical drugs must be labelled with their ingredients, and

the first major step in encouraging transparency in the pharmaceutical research industry. The Pure Food and Drug Act was passed in part due to media attention around Upton Sinclair's *The Jungle*, which revealed the grossly unsanitary conditions in the meat industry (U.S. Food & Drug Administration, 2019). As the twentieth century progressed, a number of triggering events like the publishing of *The Jungle* led to research ethics policy reforms.

The vast majority of human subjects research that is federally funded is now under the jurisdiction of the Federal Policy for the Protection of Human Subjects, also known as the Common Rule (45 C.F.R. § 46). The Health and Human Services Office of Human Research Subjects Protections states that the Common Rule governs all research done under the auspices of twenty different federal agencies, including the Department of Health and Human Services, the Department of Energy, the Department of Defense, and the National Science Foundation. The Food and Drug Administration promulgates different regulations, which are nevertheless required to align with Common Rule regulations when permitted by law (21 C.F.R. § 50).

However, agencies derive rulemaking power from the United States Congress, which creates agencies and can pass laws "that more specifically [direct] an agency to solve a particular problem or accomplish a certain goal" (Office of the Federal Register, 2020). For example, the Food, Drug, and Cosmetic Act, passed by Congress in 1938, gave the FDA power to ensure the safety of food, drugs, medical devices, and cosmetics (Food, Drug, and Cosmetic Act of 1938). Therefore, though research is most directly regulated by agencies, policy action starts in Congress.

The question then arises: Under what conditions does a narrow issue like research ethics attract the attention of members of Congress? The academic field of agenda-setting

within political science seeks to answer this. There are different common themes in how a policy issue gets on the federal agenda, one of which is the occurrence of triggering events, also known as focusing events. Birkland, referencing his own previous work and the landmark 1995 work by Kingdon, defines a focusing event as "an event that is sudden; relatively uncommon; can be reasonably defined as harmful or revealing the possibility of potentially greater future harms; has harms that are concentrated in a particular geographical area or community of interest; and that is known to policy makers and the public simultaneously" (Birkland, 1998, p.54). This definition has remained roughly consistent since the 1990s, and is applied in the next section of this paper.

As stated in Birkland's definition, focusing events drive policy change by magnetizing attention and harshly illustrating an issue that could be addressed through policy. Examples of triggering events include the aforementioned Tuskegee syphilis scandal, which led to the creation of the Belmont Report and subsequent Federal Policy for the Protection of Human Subjects. This paper demonstrates how focusing events have been a prominent driver of research ethics policy creation throughout the twentieth century, the limitations of such a system going forward, and the resultant necessity for the establishment of an independent non-governmental organization as a new driver of progress to amplify the signal of triggering events and provide policy solutions in their wake.

Analysis of Significant Historical Policy Events

Nazi Experimentation on Prisoners during the Holocaust

One of the first formative series of events for American bioethics happened on European soil. The Holocaust comprised many of the most horrific human rights abuses in modern Western history; however, the torture carried out by Nazi doctors in the course of experimentation on prisoners in concentration camps is perhaps one of the worst of these atrocities. Nazi scientists and doctors, based on their belief in Social Darwinism, racial hygiene, and Aryan racial superiority, designated Jews, homosexuals, Romani people, and other populations as "subhuman," and thus eligible for experimentation (Seidelman, 1996). However, this belief system was not developed in a vacuum. Eugenics and racial hygiene were taught at many of the top medical schools in the world, and as Seidelman states, "Many academic and scientific institutions which contributed to the evils of the Third Reich were the same organizations which had earlier helped give birth to modern medical science and medical education" (Seidelman, 1996, p.1463). Therefore, it is clear that unethical practices and beliefs of varying degrees had been woven into the fabric of research conduct from the outset. Experiments covered a number of subjects, notably "exposure to low pressure, cold, and sea water; injection of infectious viruses into open wounds; mutilation and grafting of limbs; [and] development and application of efficient methods of large-scale extermination, genocide, and sterilization" (Ivy, 1949, p.8).

Though not officially adopted by any governments or international associations, the Nuremberg Code is widely considered to be one of the most influential documents in the history of bioethics (Shuster, 1997). It was the first in a cascade of international and domestic policy works that established rights for researchers and research subjects, and was intended to strike a

balance between encouraging scientific exploration and taking the proper precautions to ensure that research is conducted in an ethical manner.

The Doctors' Trial was conducted by American judges in Germany, and the Nuremberg Code was essentially an American creation. However, this first modern instance of a scandal with implications for research ethics belies the general assumption that tragedy necessarily begets domestic legislative action. Though many Americans were made aware of the potential ethical problems within research, it was not generally thought that the same types of issues would be present in the United States. Despite wide publication of the horrors of Nazi experimentation on prisoners during the Holocaust, American scientists largely dismissed the possibility that they too could be guilty of unethical conduct. The scandal did not inspire closer inspection of domestic research practices; this implies that is more likely to get on the Congressional agenda if the unethical practice harms Americans.

Elixir Sulfanilamide Disaster

At the start of the twentieth century, drug production in the United States was regulated by the Pure Food and Drug Act of 1906. This legislation, whose passage was driven in large part by a series of sensational news articles detailing the corruption within the beef industry and the publishing of Upton Sinclair's *The Jungle*, was the first federal law to enforce food and drug quality (Pure Food and Drug Act 2014). A prominent example of Progressive Era legislation, the Pure Food and Drug Act outlawed "adulterated or fraudulently labelled food or drugs" (Pure Food and Drug Act 2014). However, it did not require that pharmaceutical companies prove that their drugs were safe for consumption, nor that companies list all of a medication's ingredients on their labels (Campbell, 2008). This glaring gap in requirements for clinical research came to

the attention of the American public in 1937, when elixir sulfanilamide, a liquid form of the breakthrough drug sulfanilamide, was put on the market (Campbell, 2008).

According to Campbell 2008, sulfanilamide effectively – and safely – combats numerous infections, including gonorrhea and strep throat. However, it was only sold in tablet or capsule form prior to the advent of elixir sulfanilamide. The Samuel E. Massengill pharmaceutical company found that sulfanilamide dissolves in diethylene glycol, a derivative of petroleum. At the time this discovery was made, it was known that diethylene glycol had been proven fatal in animals; it is unclear whether or not the Massengill company was aware of this, but they did not do any safety testing of their own on humans, and government approval was not required to market a drug in 1937 (Campbell, 2008).

Within two months, one hundred and seven people who had ingested elixir sulfanilamide had died (Campbell, 2008). Doctors reported the fatalities to the American Medical Association due to the limited oversight abilities of the FDA, which had only been created six years prior in 1931 (Campbell, 2008). The AMA, after conducting independent tests of elixir sulfanilamide because the drug's ingredients were not listed on the bottle, publicized the inclusion of diethylene glycol in the medication (Campbell, 2008). This rapid period of mobilization following an extraordinary number of deaths in a short period of time effectively pushed the federal government into action.

Due to lack of legal requirements to prove drug safety, list ingredients on the drug bottle, or gain government approval before placing a drug on the market, the FDA fined the Samuel E. Massengill company twenty-six thousand dollars over their misuse of the technical word "elixir," which denotes a liquid containing alcohol (Campbell, 2008). The election of Franklin D. Roosevelt brought about favorable political conditions for FDA chief Walter Campbell to

capitalize on the tragedy and pressure lawmakers to pass the Food, Drug, and Cosmetic Act, which had not advanced in Congress since its introduction in 1933 (Campbell, 2008). The new law empowered the FDA to require a new medication be proven safe for humans before it is placed on the market "and" that people obtain a prescription from a licensed physician before being allowed to purchase a drug (Campbell, 2008).

The elixir sulfanilamide disaster changed the way the United States understood pharmaceutical research and development. Following on the heels of Progressive Era consumer protection movements, it revealed the lack of standards for drug safety, and the consequent dangers to the public. The episode underscored the idea that clinical research is not only an essential component of drug development, but that testing for testing the safety of pharmaceutical products is necessary to protect the public.

Thalidomide Tragedy

Thalidomide was a drug marketed in the 1950s as a non-toxic sedative that also helped with morning sickness. It was put on the market in 1957 in Germany by Chemie Grunenthal, under the name Contergan (Botting, 2015). Though clinical research for the drug's safety had been investigated in animals, thalidomide had not been tested on pregnant animals (Botting, 2015). By the early 1960s it was marketed in 46 countries, not including the United States. Dr. Frances Kelsey, an FDA pharmacologist, denied the company's approval application due to their failure to prove the safety of the drug for humans. She was authorized to do this under the now-passed Food, Drug, and Cosmetics Act of 1938. Regarding the thalidomide applications for approval in the United States that began in 1960, Kelsey stated that "deficiencies in all areas were found during the initial review and in several subsequent resubmissions" (Botting, 2015).

Kelsey's concern was well-founded; from thalidomide's entrance into the German market in 1957 to 1961, evidence mounted from numerous independent doctors and researchers that thalidomide was not non-toxic, as was asserted in the original clinical papers published by researchers from Chemie Grunenthal, thalidomide's manufacturer (Botting, 2015). Anecdotal reports of peripheral neuritis in patients taking thalidomide, as well as an "epidemic of particular fetal abnormalities" without an immediate explanation, led to scrutiny of the drug (Botting, 2015). It was based on the evidence of peripheral neuritis that Dr. Frances Kelsey and the FDA blocked the sale of thalidomide in the United States (Adler, 1994). A startling number of children in Germany were born with a condition known as "phocomelia," a shortening or absence of the long bones in the arms or legs that produced seal-like limbs (Botting, 2015).

It became apparent that the original toxicity testing of thalidomide was done with a version that was poorly water-soluble; therefore, the drug was observed to be non-toxic because it was not actually being absorbed by the body in significant amounts (Botting, 2015). The version of thalidomide that Chemie Grunenthal elected to sell was "microfined thalidomide mixed with sugar solution," which is water-soluble and was later found to be highly toxic in mice (Botting, 2015). The superficiality and negligence of the initial clinical testing for thalidomide, and the bold claims of non-toxicity stemming from it, were made even more insulting by the choice to use the results to sell what was essentially a different product.

American citizens, particularly pregnant women and their children, were largely saved from the catastrophic effects of thalidomide consumption by the ability of the FDA to refuse approval of drugs for which safety had not been sufficiently demonstrated. These regulations did not exist at the time in the United Kingdom, Germany, and many other countries, which led to widespread consequences (Botting, 2015). However, approximately 20,000 Americans were still

given thalidomide, as free samples of the drug were distributed to doctors while the FDA was deliberating on its approval application, and a few cases of fetal abnormalities did occur (Botting, 2015). This loophole was subsequently closed by the 1962 Kefauver-Harris Amendment to the Food, Drug, and Cosmetics Act, which empowered the FDA to monitor all stages of drug development prior to its use in humans (Botting, 2015). It also required that pharmaceutical companies prove not only that a drug is safe, as was mandated by the original Food, Drug, and Cosmetics Act, but also effective (U.S. Food & Drug Administration, 2012).

As stated by Botting 2015, "No drug has had a greater effect than thalidomide on the extent and intensity of the preclinical investigation of potential medicines required by the regulatory authorities [globally]." The thalidomide tragedy evidenced a number of shortcomings in clinical research guidelines that had not previously garnered the attention of politicians, despite their presence throughout the short history of modern drug development.

Tuskegee Syphilis Study

In 1932, the United States Public Health Service began what became a longitudinal study in which they observed the progression of syphilis in four hundred black sharecroppers in rural Macon Country, Alabama (Brandt, 1978). At this point in history, scientists believed that diseases expressed themselves differently in different races, and such was the justification for the experiment. The research participants, who contracted syphilis independently, were not informed of the experiment, and were instead told that the National Public Health Services was going to check on them periodically and provide free treatment in exchange for their involvement. A study of this design was not uncommon in the 1930s. As aptly stated by David M. Smolin, "If the Tuskegee study had ended after that first year, it would not have been a historically

significant event, but merely one of innumerable examples of a broader trend in which physicians and researchers misinformed patients and research subjects" (Smolin, 2012). At this point in history, paternalistic conduct was the modus operandi towards the entire population, regardless of patients' race or gender; professionals in biomedical fields were not expected to consult with their patients, and in many cases patients and research subjects did not want to have full knowledge of treatment protocols, risks of treatment, or their prognoses. However, the Tuskegee syphilis study extended well into a time when the ubiquity of paternalism had passed.

The Tuskegee syphilis study comprised multiple ethical violations. Beyond a complete absence of informed consent from research participants, the investigators failed to treat the men with penicillin after its FDA approval in 1944 as an effective solution to syphilis. By the time the study was halted, at least 28 of the subjects had died from syphilis (Brandt, 1979). The study continued for 40 years until 1972, when it caught the attention of the media and became widely publicized for its gross ethical abuses. As stated by Adashi et al., "the Tuskegee Syphilis Study made it plain that the moral foundation of human subject research was in desperate need of repair," and international nonbinding documents like the Nuremberg Code and the Declaration of Helsinki were not sufficient to guarantee ethical research conduct in the United States (Adashi et al., 2018). The conduct of the National Public Health Service caught the attention of Senator Ted Kennedy, who began conducting hearings to investigate the extent of the damage done. This effort led to passage of the National Research Act of 1974, which established the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, commonly known as the Belmont Commission (Blustein, 2005). In 1978, the Commission produced the Belmont Report, the first document in the United States establishing foundational ethical principles for the governance of human subjects research. According to Blustein (2005),

"[The Belmont Report] argues that a fundamental distinguishing characteristic of research is generalizability. Scientific research is conducted to acquire knowledge that is accessible to all. That knowledge is a public good. Because research subjects assume risk in order to generate good for all, different (and higher) ethical standards apply in science than do in everyday life" (p.826)

The Report outlines three guiding principles significantly inspired by the Nuremberg Code and the Declaration of Helsinki: respect for persons, beneficence, and justice. Respect for persons is a recognition of research subjects' autonomy and valuing of wellbeing; it is from this tenet that the concept of informed consent arises (Blustein, 2005). Beneficence is a recognition that "risk is only justified in proportion to the expected benefits [of research]" (Blustein, 2005). This calculation is complex and varies significantly between unique research situations, but essentially requires a prioritization of risk reduction and an examination of how worthwhile a proposed research project truly is. The final principle, justice, refers to "the fair and equitable distribution of research benefits and burdens" (Blustein, 2005). The Belmont Report calls attention to the reality that, as evidenced by the Tuskegee scandal, "welfare patients, particular racial and ethnic minorities, or persons confined to institution are being systematically selected simply because of their easy availability, their compromised position, or their manipulability, rather than for reasons directly related to the problem being studied." In other words, it is not ethical to take advantage of people's lack of certain privileges for the sake of research. Choice of research subjects should be based in their population's relevance to the research question, and the potential of their population to benefit from the knowledge resulting from the study.

The Belmont Report, published in the Federal Register in 1979, revolutionized human subjects research conduct in the United States. Had it been in place prior to the Tuskegee study,

the men would not have been chosen based on their economic situation and lack of access to other medical care. If they had been chosen and fully informed of the researchers' intentions, the men likely would not have given their consent. The study probably would not have proceeded at all, because risk to the subjects certainly outweighed the benefits of the knowledge gained.

The Belmont Commission also released a recommendation for the creation of institutional review boards (IRBs), an integral part of ethics enforcement in human subjects research today. Requirements for IRB approval and the ethical tenets outlined in the Belmont Report were packaged together as a set of regulations governing research sponsored by the then-present Department of Health, Education, and Welfare in 1981 (Blustein, 2005). Later, these regulations were modified and published as the Federal Policy for the Protection of Human Subjects, also known as the Common Rule (Blustein, 2005). The Common Rule remains the law of the land for ethical research conduct.

Conclusions

Discussed above are just a few of the historical examples from the twentieth century in which a lack of human subjects protections or due diligence in pharmaceutical research led to large-scale harm for the general populace. Other cases, such as that of the Jewish Chronic Disease Hospital cancer study in 1963[1], the Willowbrook hepatitis study from 1956 to 1971[2], the Monster Study of stuttering children in the 1930s[3], and Cold War human radiation experiments[4] reinforce the idea that regulation of research is necessary to improve and maintain the ethical

[1] See Lerner (2004) for more information on the Jewish Chronic Disease Hospital cancer study
[2] See Rothman (1982) for more information on the Willowbrook hepatitis study
[3] See Silverman (1988) for more information on the Monster Study
[4] See Advisory Committee on Human Radiation Experiments (1996) for more information on the Cold War human radiation experiments

integrity of the research community. As such, it is worthwhile to investigate how advocacy for research ethics policy progress can be executed most effectively.

Obstacles to Proactive Policy Advocacy

In the interest of preventing future ethics abuses in research, it would be preferable to shift to a more proactive model of policy advocacy. Reasoning for this has both moral and practical dimensions. It is immoral that, historically, the United States has only pursued protective regulations following harm to American citizens that occurred because those protections did not exist. Academic work in the field of research ethics has become sufficiently sophisticated to where problems are recognized and addressed, and experts are available to help policymakers resolve holes in current regulations. Practically, the current reliance on triggering events is unsustainable; as regulation of research increases, potential for gross ethical violations decreases, therefore lowering the probability that another triggering event will occur. This cycle outlaws the worst of ethics abuses but leaves more systemic and complex issues, like lack of inclusion of underrepresented groups in research that would otherwise benefit them, intact. Following this trend, the United States is at risk of slowing progress in research ethics policy, barring increased involvement from interest groups for whom research ethics is not a top priority. Though individual entities conducting research may have their own ethical conduct standards that are more rigorous than the federal regulations of the time, they have little to gain by advocating for these standards to become blanket laws set by the government. Lack of stricter formal regulations allows individual entities to optimally craft standards for their own operations.

Shifting to a more proactive research ethics policymaking environment would be difficult, as the obstacles are manifold. No major advocacy organizations are specifically devoted to this issue; research ethics is often a mid- to low-level policy priority for biomedical and academic groups. This is evidenced by the groups who responded to the notice of proposed rulemaking that preceded the final version of the 2017 revision of the Common Rule. Commenters representing organizations primarily worked for institutions of higher learning, national scientific and medical associations, and health-related state agencies. Organizations that are specifically committed to research ethics, such as private IRB companies, also shared their input on the proposed regulations, but these were a small minority of overall submissions.

For interest groups like academic institutions and biomedical groups whose policy concerns are wide-ranging, commenting on proposed regulations is an inexpensive way to make their preferences heard. It has also proved to be an effective strategy, as those who comment early in the commenting period often succeed in influencing the content of the final rule (Naughton et al., 2009). However, advocacy on Capitol Hill takes time and monetary investment in the form of a dedicated governmental relations professional or team. As a result, niche issues related to research ethics are often deprioritized in the interest of more ostensibly pressing issues. For example, research institutions may have an interest in diversifying the pool of human research subjects participating in their research, but may put it on the back burner while focusing their efforts on obtaining better tax benefits in a bill set to pass that session.

One type of interest group frequently working in the research ethics policy space is associations of people with personal stakes in the future and integrity of research, like the

Cystic Fibrosis Foundation or the National Organization for Rare Disorders (both of whom have commented on the notice of proposed rulemaking regarding the 2017 revision to the Common Rule). These groups stand to benefit from increased research quality. For example, the National Organization for Rare Disorders may represent subpopulations with disorders that affect people of many different racial backgrounds. The organization may then be incentivized to use resources to advocate for stronger requirements for diversity in clinical trial research subjects, given that disparities in how people from different racial backgrounds metabolize medications is well documented (Wood and Zhou, 1991; Johnson, 1997; Xie et al., 2001). However, this type of advocacy group may also prioritize expedient research in order to get its members help more quickly. While there is an ethical debate over the proper balance between benefits of faster drug approval and maintaining the high quality of research, organizations of this ilk are not sufficient to establish a balanced advocacy push in the research ethics policy area. There is consistent potential for these groups' other interests to overshadow or influence their stance on ethics issues.

Another potential roadblock is that an advocacy group specifically devoted to elevating ethical conduct in the course of research would necessarily need to be comprised at least largely of academic experts at its inception. This is a challenging kind of policy to navigate, as ethics concerns frequently oppose arguments for faster approval of research protocols and new clinical drugs. The latter is especially difficult ground, given that there are many people who suffer from medical issues that have yet to be cured or for which current treatment options could be more effective or less deleterious to quality of life. Given these issues, a grassroots swelling of support for pure research ethics advocacy is extremely unlikely. People generally want easier access to health resources and less

bureaucratic red tape, both of which could be construed as parts of the research ethics advocacy mission. It would therefore require experts in the field to form a group based in the formal studies of ethics and various research disciplines, in addition to community stakeholders, to comprise a starting group.

Advocacy organizations in the research ethics policy space must also deal with political barriers. Health care and funding for research and development frequently overshadow research ethics in party platforms. The finite amount of resources and political capital these groups possess have higher potential return in such areas. The official party platforms are just one way for an issue to get on legislators' radars, and perhaps not the most effective way, but platforms are inarguably a major outward-facing expression of a political party's values. The niche nature of research ethics means that visibility through this medium is unlikely. In general, it is more politically advantageous for politicians to care in the wake of a negative event, as this makes them appear responsive to citizen concerns. As was mentioned previously, this avenue for attention is becoming even less promising as protective regulations increase. The primary issues within research ethics now, such as effectiveness of informed consent documents, diverse population samples in research subject pools, and the importance of cultural proficiency, will not generate the same amount of media attention and subsequent investment of political capital as historical scandals did (Bloswick and Skowron, 2015; Quinn et al., 2013).

The people who are negatively affected by today's suboptimal research practices are also typically not people most likely to inspire national sympathy. People who participate in research and thus are harmed by ethical violations in the course of research often are not privileged (Quinn, 2013). It is likely that a paid research study will mostly

attract subjects who need the money. Likewise, patients with an ailment not yet cured are more likely to volunteer themselves for a clinical trial. Thus, these people are in compromised positions; they could stand to benefit from the results of the research in which they are partaking or may be compensated for their time with a sum of money relatively large for them. While these realities may make participation worthwhile to the individual subject, it does not absolve researchers of imperfect conduct or research design.

Creating the Solution: An Evolving World of Research Ethics Advocacy

Given the limitations discussed in the previous section, creating favorable shifts in research ethics advocacy appears to be a steep uphill battle. In fact, they evidence the need for a new strategy, one that may leverage some of the obstacles into strengths. The field of research ethics needs to establish an independent, nonprofit interest group if current and future issues are going to be handled more proactively.

Currently, there is no law that mandates all research in the United States be regulated by the federal government; instead, only research that is federally funded is bound by these rules. In the case of research for the purpose of drug or medical device development, FDA regulations must be adhered to in order for the product to be approved. As a result, much privately funded research is not required to follow many of the federal agency regulations, though many entities like research universities voluntarily comply with Common Rule standards.

Though most regulation of human subjects research occurs through the federal agencies, the impetus for policy change does not necessarily originate within the agencies or from the White House administration. People interested in instituting change within research conduct are

underutilizing the power of Congress to allow – or require – agencies to evolve their policies. It is necessary to expand advocacy efforts on Capitol Hill to ensure that policy work relevant to research ethics becomes more proactive, because the legislative branch is designed to be the most responsive to the concerns of domestic groups and United States citizens.

A dedicated advocacy group would meet several different needs currently lacking in the research ethics policy space. As was mentioned in prior sections, a central method by which individuals and organizations may provide their input on policy change is through commenting on new regulations being proposed by federal agencies. This is inherently a reactive practice, and necessarily limited to the topics which have already been deemed worthwhile by the federal government. One key advantage of outside advocacy organizations is the freedom to influence social and political conversations in order to promote whatever issues they see fit. This ability is key for an organization like a hypothetical research ethics interest group, as it would be attempting to garner attention for issues not currently being considered by policymakers. For example, only approximately 70% of human subjects research (not including clinical drug trials) is funded and therefore regulated by federal agency regulations (Gelsinger and Shamoo, 2008). An initiative to make all domestic research regulated by these rules, which would be a major policy shift likely protested by industry, would require a legislative lobbying effort by an interest group. Many other currently prominent issues within research ethics, like increased requirements for cultural proficiency of researchers with their human populations of interest, could also be navigated best through strategic political advocacy.

Another advantage that builds directly on the former is the ability of nonprofits to collect and then amplify the voices of individual citizens who have little political power as lone actors. This includes both academics with little experience in politics and anyone with a grassroots

interest in research ethics issues. Bioethicists focusing on research ethics may have an interest in influencing policy, but currently do not have an avenue for doing so besides providing comments on proposed agency regulations or other smaller-scale efforts. Bioethicists working collectively with public policy experts and governmental relations professionals would have a more direct line of communication with the federal government that conveys an intent for consistent advocacy across time.

As one of the missions of a research ethics advocacy group would be to empower human research subjects, this organization must not silo itself into only providing expert input on the legislative agenda. It should also mimic entities like the American Civil Liberties Union (ACLU) and National Association for the Advancement of Colored People (NAACP) in providing a place where individuals can gain assistance in learning their rights as research subjects and acting as a representative for them. This is a crucial service because federal agencies overseeing proper research conduct do not have sufficient resources to effectively enforce current regulations. A paper by Paul Gelsinger and Adil E. Shamoo states that, as of 2008, the Food & Drug Administration had only two hundred investigators for over 350,000 sites where clinical trials were being conducted; thus, problems are often reported to the FDA after research has already concluded (Gelsinger and Shamoo, 2008). If an independent research ethics group served as a resource for people who experience unethical practices, it could continually improve its understanding of regulatory areas most in need of improvement.

In addition, a research ethics advocacy organization would have the flexibility to form coalitions with the stakeholders currently doing advocacy work in this area – such as universities and medical interest groups – when interests align, and also to break with these organizations when their other interests outcompete the ideal policy outcome from a research ethics standpoint.

It is unlikely that the current stakeholders would react negatively to the creation of a research ethics group, as they are all interested in appropriate research conduct. Many medical schools and universities, which do have existing relationships in various forms with policymakers, house bioethics centers, and thus would likely partner with an independent organization on many issues. Coalition-building magnifies the influence of advocacy efforts and would be crucial in affecting positive change within research ethics policy issues.

One potential obstacle in the formation of a research ethics interest group is the typical hesitancy of academics to enter into the political sphere. Research is a time-consuming profession, and forays into politics require concerted effort over long periods of time to make an impact. Alternatively, some may feel that their energy is better spent influencing the general public's views of human subjects research conduct and related topics. This is a legitimate potential issue regarding recruitment of experts to serve as policy resources, particularly given the relatively small size of the research ethics academic population. However, an interest group would not only be comprised of professional bioethicists, but also policy experts and governmental relations specialists that would apply academics' knowledge to political advocacy. Furthermore, specialized knowledge in any field that affects the welfare of society, as is the case with research ethics, should not simply sit on the shelf.

Another concern is sources of funding for an advocacy organization, given that one of the major reasons for creating such a group would be to establish independence from larger entities with broad ranges of policy concerns. Like any nonprofit, a research ethics interest group will need to establish a development arm to drive donations from philanthropists. Efforts to generate interest from donors in research ethics, however, should not resort to scare tactics that demonize researchers. The express purpose of a research ethics organization would be to maintain and

improve the integrity of scientific research in the United States through proper regulation and accountability measures; initiatives that reduce trust in scientists would be counterproductive to this mission.

The question of funding is in part why an independent research ethics policy group would most organically stem from an existing entity, such as the Hastings Center, that already possesses a donor base. From this starting point, the organization could position itself as a resource for pharmaceutical companies, universities, and other businesses and institutions who conduct biological or biomedical research. A nonprofit advocacy organization focused on improving the integrity of the research process in an unbiased fashion would be a prime candidate for these businesses' philanthropic arms. By leveraging a public image as a societal good to garner support from other stakeholders in the research ethics policy sphere, a research ethics policy group can establish a sustainable fundraising plan.

This financial relationship with research institutions and businesses and reputation as a reliable policy source may serve to blunt opposition to policy initiatives that the research ethics organization supports. It may foster more of a conversation about proper research ethics policy than an oppositional battle, in which the research ethics organization can advocate for more proactive policy. Such an arrangement will often benefit the research ethics organization, especially in its early years as it builds relationships and name recognition. However, there will still be topics on which stakeholders with other priorities and the research ethics policy group will differ. Among these will likely be issues with the potential to cost researchers more time or money without significant personal or organizational benefit. For example, pregnant women have been historically excluded from pharmaceutical and other biomedical research, resulting in a severe dearth of knowledge on how drugs affect them despite evidence that treatments affect

them differently (Ballantyne, 2019). Involving more pregnant women in research is complex and represents an added cost for pharmaceutical development, but it does not change the fact that this lack of knowledge endangers women who must take medications to address other conditions. Advocating for increased inclusion of pregnant women in biomedical research and providing insight on how to do so ethically may set a research ethics policy group against stakeholders reluctant to take on the challenge. However, this is exactly the kind of scenario that such a group would be created to address.

Potential avenues of action for a research ethics advocacy organization are numerous and pursuing all of them from the outset would be unrealistic. However, it is clear that an interest group of this nature, regardless of its initial emphases, would fill a large gap in the advocacy space and have the ability to scale up its projects as resources permit.

Conclusion

Through the study of major research ethics policy events of the twentieth century, it is clear that most were preceded by triggering events, which Birkland defines as sudden events with concentrated harms that are known to politicians and the public simultaneously (Birkland, 1998). In the case of research ethics, triggering events often serve to illustrate what was before an abstract, esoteric issue, and demonstrate the need for change to policymakers. This process followed the elixir sulfanilamide disaster, the Tuskegee syphilis scandal, and the human radiation experiments of the Cold War. Research ethics policy progress, particularly the gradual empowerment of the FDA and the creation of the Federal Policy for the Protection of Human Subjects (also known as the Common Rule), has greatly reduced the occurrence of grossly unethical conduct in human subjects research.

However, a decrease in the number of newsworthy ethics abuses in the course of research does not mean that all human subjects research in the United States is now effectively regulated. Issues such as the legitimacy of subjects' informed consent to participate in a study and rigorous risk-benefit analysis of proposed research are examples of contemporary problems with potential policy solutions. It is also important to note that research ethics work is not the enemy of researchers; further refinement of IRB approval processes and the cutting back of unecessary bureaucratic red tape are also prominent issues in the research ethics space, as was evidenced by the attention given to those issues in the revision of the Common Rule in 2017.

Research into agenda setting demonstrates that much federal policy in the United States is reactionary, particularly in fields that require understanding of technical knowledge. Research ethics suffers twice over from this perspective, in that a sophisticated understanding of it requires background in both hard science and ethics. The knowledge gap between experts in the research ethics field, other stakeholders, and policymakers must be bridged in order for policy change to originate from Congress.

In the past, that bridging was motivated by a triggering event that compelled legislators to understand the issue at hand. As the potency and frequency of research ethics abuses wanes with time and increased regulation, something new must drive the bridging of the gap. The foundation of a nonpartisan, independent research ethics advocacy organization would best serve this function, providing unbiased information resources that current stakeholders in the research policy arena cannot. The basic tools and personnel for an advocacy organization are already in existence; this is a call for professionals who specialize in research ethics, whether in the legal, academic, medical, or other fields, to mobilize their knowledge for policy-oriented progress.

This thesis is also a building block for further research into possibilities for the union of bioethics and policy. While the intersection of bioethics and law is a lively field, application of bioethics to policy requires further development. Future agenda-setting analysis into the behavior of universities, research institutes, pharmaceutical companies, and other entities conducting human subjects research regarding research ethics regulation would greatly contribute to the research ethics policy knowledge base. In addition, comparative studies of advocacy in research ethics versus other niche policy areas requiring technical knowledge would help burgeoning research ethics advocacy efforts to navigate the political process more effectively.

References

Adashi, E. Y., Walters, L. B., & Menikoff, J. A. (2018). The Belmont Report at 40: Reckoning with time. *American Journal of Public Health; 108*(10), 1345-1348. https://doi.org/10.2105/AJPH.2018.304580

Adler, T. (1994). The return of thalidomide: A shunned compound makes a scientific comeback. *Science News, 146*(26/27), 424-425. https://doi.org/10.2307/3978310

Advisory Committee on Human Radiation Experiments. (1996). *Advisory committee on human radiation experiments – final report*. Retrieved from https://bioethicsarchive.georgetown.edu/achre/final/report.html

Ballantyne, A. (2019). Pregnant women can finally expect better. *Hastings Center Report, 29*(1), 10-11. https://doi.org/10.1002/hast.971

Birkland, T. A. (1998). Focusing events, mobilization, and agenda setting. *Journal of Public Policy*, *18*(1), 53-74. Retrieved from https://www.jstor.org/stable/4007601

Bloswick, A., & Skowron, H. A. (2015). Informed consent documentation in pharmaceutical industry-sponsored clinical trials. *Ethics & Medicine*, *31*(1), 51-58.

Blustein, J. (2005). Toward a more public discussion of the ethics of federal social program evaluation. *Journal of Policy Analysis and Management*, *24*(4), 824-846. Retrieved from https://www-jstor-org.ezproxy.lib.utexas.edu/stable/30162683

Botting, J. (2015). The history of thalidomide. In R. Botting (Ed.), *Animals and medicine: The contribution of animal experiments to the control of disease* (pp. 183-198). Open Book Publishers. Retrieved from https://www.jstor.org/stable/j.ctt15m7ng5

Brandt, A. M. (1978). Racism and research: The case of the Tuskegee syphilis study. *The Hastings Center Report*, *8*(6), 21-29.

Callahan, D. (2012). *The roots of bioethics: Health, progress, technology, death*. New York, NY: Oxford University Press.

Calkins, L. M. (2008). Historical records and homeland security: The declassification and retraction of government documents on human radiation experiments. *International Journal of Feminist Approaches to Bioethics*, *1*(2), 165-173. Retrieved from https://www-jstor-org.ezproxy.lib.utexas.edu/stable/40339183

Campbell, B. C. (2008). 1937 Elixir Sulfanilamide Tragedy. In B. C. Campbell, *Facts on File Library of American History. Disasters, Accidents, and Crises in American History: A Reference Guide to the Nation's Most Catastrophic Events* (pp. 272-274). New York, NY: Facts on File. Retrieved from https://link-gale-com.ezproxy.lib.utexas.edu/apps/doc/CX4085100140/GVRL?u=txshracd2598&sid=GVRL&xid=c9f8ea98

FDA Protection of Human Subjects 21 C.F.R. § 50 (1991).

Federal Policy for the Protection of Human Subjects, 45 C.F.R § 46 (2017).

Gelsinger, P., & Shamoo, A. E. (2008). Eight years after Jesse's death, are human research subjects any safer? *The Hastings Center Report*, *38*(2), 25-27.

Hilts, P. J. (1993, March 25). F.D.A. ends ban on women in drug testing. *New York Times*, p. B8.

Ivy, A. C. (1949). Statement by Andrew C. Ivy, M.D. In A. Mitscherlich & F. Mielke (Authors) & H. Norden (Trans.), *Doctors of infamy: The story of the Nazi medical crimes* (pp. 6-8). Pickle Partners Publishers.

Johnson, J. A. (1997). Influence of race or ethnicity on pharmacokinetics of drugs. *Journal of Pharmaceutical Sciences*, *86*(12), 1328-1333. https://doi.org.ezproxy.lib.utexas.edu/10.1021/js9702168

Jones, B. D., & Baumgartner, F. R. (2005). A model of choice for public policy. *Journal of Public Administration Research and Theory, 15*(3), 325-351. https://doi-org.ezproxy.lib.utexas.edu/10.1093/jopart/mui018

Jones, J. H. (1993). *Bad blood: The Tuskegee syphilis experiment* (New and expanded ed.). New York, NY: The Free Press.

Kingdon, J. W. (1995). *Agendas, alternatives and public policies*. New York: Harper Collins College.

Lee, L. M., & McCarty, F. A. (2016). Emergence of a discipline? Growth in U.S. postsecondary bioethics degrees. *The Hastings Center Report, 26*(2), 19-21. Retrieved from https://www.jstor.org/stable/44159427

Lerner, B. H. (2004). Sins of omission: Cancer research without informed consent. *New England Journal of Medicine*, *351*(7), 628-630. Retrieved from http://ezproxy.lib.utexas.edu/login?url=https://search-proquest-com.ezproxy.lib.utexas.edu/docview/ 223939208?accountid=7118

National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. (1979). *The Belmont report: Ethical principles and guidelines for the protection of human subjects of research.* Retrieved from https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/read-the-belmont-report/index.html

Naughton, K., Schmid, C., Webb Yackee, S., & Zhan, X. (2009). Understanding commenter influence during agency rule development. *Journal of Policy Analysis and Management, 28*(2), 258-277. https://doi.org/10.1002/pam.20426

The Nuremberg Code. (1949). Retrieved from National Institutes of Health website: https://history.nih.gov/research/downloads/nuremberg.pdf

Office of the Federal Register. *A guide to the rulemaking process*. (n.d.). Retrieved March 3, 2020, from Office of the Federal Register website: https://www.federalregister.gov/uploads/2011/01/the_rulemaking_process.pdf

Pure food and drug act. (2014). In E. Foner, & J. A. Garraty (Eds.), *The reader's companion to American history*. Houghton Mifflin. Credo Reference: http://ezproxy.lib.utexas.edu/login?url=https://search.credoreference.com/content/entry/rcah/pure_food_and_drug_act/0?institutionId=4864

Quinn, S. C., Cass, N. E., & Thomas, S. B. (2013). Building trust for engagement of minorities in human subjects research: Is the glass half full, half empty, or the wrong size? *American Journal of Public Health*, *103*(12), 2119-2121.

Rothman, D. J. (1982). Were Tuskegee and Willowbrook 'studies in nature'? *Hastings Center Report*, *12*(2), 5-7. Retrieved from https://www-jstor-org.ezproxy.lib.utexas.edu/stable/3561798

Seidelman, W. E. (1996). Nuremberg lamentation: For the forgotten victims of medical science. *British Medical Journal*, *313*(7070), 1463-1467. Retrieved from https://www-jstor-org.ezproxy.lib.utexas.edu/stable/29733731

Shuster, E. (1997). Fifty years later: The significance of the Nuremberg Code. *New England Journal of Medicine*, (337), 1436-1440. https://doi.org/ 10.1056/NEJM199711133372006

Silverman, F. H. (1988). The "monster" study. *Journal of Fluency Disorders*, *13*(3), 225-231. https://doi.org/10.1016/0094-730X(88)90049-6

Sinclair, U. (1906). *The jungle*. Doubleday.

Smolin, D. M. (2012). The Tuskegee syphilis experiment, social change, and the future of bioethics. *Faulkner Law Review, 3*(2), 229-251.

U.S. Congress. (1934). *United States Code: Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301-392 Suppl. 5.* [Periodical] Retrieved from the Library of Congress, https://www.loc.gov/item/uscode1934-006021009/.

U.S. Food & Drug Administration (2012). *Kefauver-Harris Amendments Revolutionized Drug Development* [Fact sheet]. Retrieved March 17, 2020, from U.S. Food & Drug Administration website: https://www.fda.gov/consumers/consumer-updates/kefauver-harris-amendments-revolutionized-drug-development

U.S. Food & Drug Administration (2019). Part I: The 1906 Food and Drugs Act and its enforcement. Retrieved March 27, 2020, from U.S. Food & Drug Administration website: https://www.fda.gov/about-fda/fdas-evolving-regulatory-powers/ part-i-1906-food-and-drugs-act-and-its-enforcement

Vane, J. & Kalvas, F. (2013). The Agenda-Setting Effect of Focusing Events: A Case Study of the Church Restitutions Issue. *Sociologia - Slovak Sociological Review, 45*(3), 290–311. Retrieved from http://search.proquest.com/docview/1629331376/

Wood, A. J., & Zhou, H.H. (1991). Ethnic differences in drug disposition and responsiveness. *Clinical Pharmacokinetics*, 20(5), 350-373. https://doi.org/ 10.2165/00003088-199120050-00002

World Medical Association. (2013). World Medical Association Declaration of Helsinki: Ethical principles for medical research involving human subjects. *Journal of the American Medical Association,* 310(20), 2191–2194. https://doi.org/10.1001/jama.2013.281053

Xie, H.G., Kim, R.B., Wood, A.J., & Stein, C.M. (2001). Molecular basis of ethnic differences in drug disposition and response. *Annual Review of Pharmacology and Toxicology*, 41, 815-850. https://doi.org/10.1146/annurev.pharmtox.41.1.815

Author Biography

Kendall Hagman is a fourth-year Polymathic Scholar from Arlington, Texas. She will graduate in May 2020 with a B.S.A Biology, as well as a certificate in Evidence & Inquiry, a certificate in Core Texts & Ideas, and a minor in Government. Following graduation, Kendall will begin her studies at the George Washington University Law School in Washington, DC as a Presidential Merit Scholar. She hopes to establish a career in science and health administrative law at one of the federal agencies.

On campus, Kendall is a member of the Natural Sciences Council, in which she has worked on the Professional Development Committee, Legislative Committee, and the Diversity & Inclusion Committee. She also founded 314 Action UT Austin, the campus branch of a national pro-science political action committee. The fall of her junior year, Kendall interned for Senator Amy Klobuchar in Washington, DC as a UT System Archer Fellow, and the following summer participated in the Sherwin B. Nuland Summer Institute in Bioethics at Yale University. She considers these experiences in policy and bioethics instrumental in the evolution of her career goals. Kendall's other hobbies include intramural volleyball, puzzling, and exploring Austin coffee shops.